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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,099	01/16/2001	Rebecca E. Cahoon	BB 1159	3054

7590

06/03/2003

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/03/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,099

Applicant(s)

Cahoon et al.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-42 and 46 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36, 39-42, and 46 is/are rejected.
- 7) ☒ Claim(s) 37 and 38 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 16, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other _____

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DETAILED ACTION

1. In the **AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.111** dated 2/26/2003 (Paper No. 15), Applicants have canceled claims 43-45.

2. Claims 34-42 and 46 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 34-36, 39-42, and 46 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 5 which encodes a polypeptide having 3-dehydroquinase synthase activity and an isolated polynucleotide encoding a polypeptide having 3-dehydroquinase synthase activity, wherein the amino acid sequence of the polypeptide comprises the amino acid sequence of SEQ ID NO: 6; does not reasonably provide enablement for any isolated polynucleotide encoding a polypeptide having 3-dehydroquinase synthase activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO: 6 have at least 80%, 90%, or 95% identity based on the Clustal alignment method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed 2/26/2003 (Paper No. 15) have been fully considered but they are not persuasive. Applicants' position is that the combination of the instant specification and knowledge within level of one of ordinary skill in that art at time of filing would enable one of ordinary skill in that art to make and use the claimed invention without undue experimentation. However, the Examiner disagrees for the reasons of record and the reasons stated below.

The Appendix A attached to Paper No. 15 which shows alignments of various amino acid sequences of dehydroquinase synthase and provides information on conserved, invariant, and catalytic amino acids of the enzyme was not originally filed with the instant application. Hence, guidance with regard to the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved was not available at the time of

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filing to enable one of ordinary skill in that art to make and use the claimed invention without undue experimentation. Furthermore, since Carpenter et al. reference cited in Paper No. 15 which discusses the proposed critical catalytic amino acids dehydroquinase synthase obtained from the crystal structures was not published prior to the filing of the instant application, one of ordinary skill in that art to cannot make and use the claimed invention without undue experimentation since knowledge of the crystal structures of dehydroquinase synthase was not available at time of filing of 60/093,611 which was filed on 7/21/1998.

Thus, searching for the specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in any polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 6 in order to make a polypeptide that has an amino acid sequence has at least 80%, 90%, or 95% identity to SEQ ID NO: 6 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polynucleotide encodes a protein that has 3-dehydroquinase synthase activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Claims 39-42 and 46 which depend from defective claim 34 are also rejected because they do not correct the defect of claim 34.

Amending the claims to recite that the isolated polynucleotide encodes a dehydroquinase synthase comprising the amino acid sequence of SEQ ID NO: 6 may overcome the rejection.

Claim Objections

5. Claims 37 and 38 stand objected for reasons of record as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

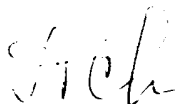
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF


CHRISTIAN L. FRONDA
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